UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

FEDERAL TRADE COMMISSION, Plaintiff, v. SHIRE VIROPHARMA INC., Defendant.	Civil Action No. 17-cv-00131-RGA

PLAINTIFF FEDERAL TRADE COMMISSION'S
OPPOSITION TO SHIRE VIROPHARMA INC.'S MOTION TO DISMISS

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The Federal Trade Commission ("FTC") brought this suit for injunctive and monetary equitable relief to challenge Shire ViroPharma's ("ViroPharma") unprecedented abuse of the Food and Drug Administration's ("FDA") citizen-petitioning process. Over six years, ViroPharma made 46 separate filings to the FDA and federal courts, delaying FDA approval of generic Vancocin Capsules and costing consumers and other payers hundreds of millions of dollars. The FDA ultimately deemed ViroPharma's years-long campaign "unsupported," "lack[ing] merit," and "an improper use of the citizen petition process." Now, ViroPharma challenges the FTC's well-established authority to bring such claims in federal court to protect American consumers, and erroneously invokes the limited protection from antitrust liability reserved for legitimate petitioning activities. ViroPharma's arguments not only fail as a matter of law, but also improperly rely on factual disputes that cannot be resolved on a motion to dismiss. In sum, ViroPharma's motion to dismiss should be denied in its entirety.

NATURE AND STAGE OF THE PROCEEDINGS

On February 7, 2017, the FTC filed its Complaint (D.I. 2) under the authority granted to it by Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), alleging that ViroPharma's sham petitioning violated the antitrust laws and requesting a permanent injunction and monetary equitable relief. ViroPharma moved to dismiss the Complaint on April 10, 2017. D.I. 19.

SUMMARY OF ARGUMENT

1. The FTC may seek equitable relief under Section 13(b) of the FTC Act in the form of a permanent injunction where it has reason to believe a defendant's unlawful activities are likely to recur or when it seeks other equitable relief.

2. The Complaint's allegations plausibly allege that ViroPharma's anticompetitive conduct is likely to recur.

3. Even if the Complaint had not adequately alleged likelihood of recurrence, the FTC may maintain an independent action for monetary equitable relief under Section 13(b).

4. The Complaint's allegations that ViroPharma petitioned the FDA and courts 46 times in seven proceedings suffice to allege that ViroPharma engaged in serial petitioning.

5. The Complaint adequately alleges sham petitioning because ViroPharma acted without regard to the petitions' merits and used the governmental process (as opposed to the outcome of that process) to obstruct entry of generic Vancocin Capsules.

6. Even assuming *arguendo* that the standard for a single sham petition should apply in this case, the Complaint plausibly alleges that ViroPharma's filings were objectively baseless.

7. ViroPharma's arguments as to the FTC's authority to bring this case and *Noerr-Pennington* protection raise issues of disputed fact not resolvable on a motion to dismiss.

STANDARD OF REVIEW

In deciding a motion to dismiss pursuant to Rule 12(b)(6), a court must "accept as true all allegations in the plaintiff's complaint as well as all reasonable inferences that can be drawn from them, and . . . construe them in a light most favorable to the non-movant." *Monroe v. Beard,* 536 F.3d 198, 205 (3d Cir. 2008). A complaint must contain sufficient factual matter to state a facially plausible claim to relief. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). This standard is satisfied when the complaint's factual content "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.*[1]

[1] To the extent ViroPharma also alleges a lack of jurisdiction under Rule 12(b)(1) regarding the FTC's authority to raise a claim under Section 13(b) of the FTC Act, courts apply the same standard as a Rule 12(b)(6) motion to dismiss for failure to state a claim. *See In re Schering Plough Corp. Intron/Temodar Consumer Class Action,* 678 F.3d 235, 243–44 (3d Cir. 2012).

STATEMENT OF FACTS

Facing the threat of generic competition to its lucrative monopoly on Vancocin Capsules, ViroPharma "inundated the FDA with regulatory and court filings—forty-six in all"—over a six-year period to delay the FDA's approval of generic Vancocin Capsules. D.I. 2 ¶ 1. To effect its anticompetitive scheme, ViroPharma made repetitive, serial, and meritless filings to obstruct and delay FDA approval of generic Vancocin Capsules, a drug used to treat a potentially life-threatening gastrointestinal infection, costing patients and other purchasers hundreds of millions of dollars. D.I. 2 ¶ 1.

I. The Drug Approval Process and Citizen Petitions

A company seeking to market a new pharmaceutical product in the United States must file a New Drug Application ("NDA") with the FDA. D.I. 2 ¶ 10. A company seeking to market a generic drug may instead file a less onerous Abbreviated New Drug Application ("ANDA"). D.I. 2 ¶ 13. Unlike an NDA applicant, an ANDA applicant need not demonstrate the proposed generic's efficacy and safety, and may instead rely on the approved NDA, while demonstrating that its proposed generic drug is bioequivalent to the approved NDA or that the rate and extent to which the active ingredient in the proposed generic drug becomes available at the site of drug action is similar to that of the approved branded drug. D.I. 2 ¶¶ 13–14. The FDA has considerable flexibility in determining how an ANDA applicant may determine bioequivalence, including requiring in vivo or in vitro testing. D.I. 2 ¶ 16.

A citizen petition is a request that the FDA take (or refrain from taking) administrative action. D.I. 2 ¶ 18. The FDA reviews and responds to every citizen petition filing it receives, including any supplements or amendments. D.I. 2 ¶ 20. The FDA generally resolves and responds to issues and arguments raised in citizen petition filings, including supplements and amendments, before or at the same time it approves a generic application. D.I. 2 ¶ 20.

II. Vancocin Capsules

Vancocin Capsules are an oral antibiotic indicated for treatment of Clostridium difficile-associated diarrhea ("CDAD"), a potentially life-threatening illness. D.I. 2 ¶ 30. In 1985, Eli Lilly submitted an NDA for Vancocin Capsules, which was approved in April 1986. D.I. 2 ¶¶ 33, 36. That NDA did not include clinical endpoint studies.[2] D.I. 2 ¶ 33. ViroPharma acquired the rights to Vancocin Capsules in November 2004. D.I. 2 ¶ 37. ViroPharma recognized that Vancocin Capsules were a "sole source item" that faced "no competition in its current space" as a life-saving drug for CDAD. D.I. 2 ¶ 40. From 2004 through 2011, Vancocin Capsules were ViroPharma's largest revenue-generating product, accounting for all of the company's net revenues until 2009 and more than half of its net revenues in 2011, growing to almost $300 million in sales by 2011. D.I. 2 ¶ 38.

Although Vancocin Capsules were vulnerable to generic competition, given the lack of patent protection or other regulatory exclusivities, potential generic competitors faced a barrier in the FDA's recommendation that required expensive and time-consuming clinical endpoint studies to demonstrate bioequivalence. D.I. 2 ¶ 42. By the time ViroPharma had purchased the rights to Vancocin Capsules in 2004, however, the FDA had convened a panel of independent experts to reconsider this guidance. D.I. 2 ¶ 43. ViroPharma grew increasingly concerned that the FDA might permit generic applicants to establish bioequivalence through in vitro dissolution data instead of clinical endpoint studies. D.I. 2 ¶ 44.

In February 2006, the FDA advised generic manufacturers that bioequivalence for Vancocin Capsules could be established through in vitro dissolution testing. D.I. 2 ¶ 47. Akorn, a

[2] Clinical endpoint studies assess the safety and efficacy of a proposed drug in a patient population. A placebo may be included in the study as a control for clinical effect. D.I. 2 ¶ 11.

generic drug manufacturer, submitted its ANDA for Vancocin Capsules to the FDA on March 5, 2007. D.I. 2 ¶ 48. Two other applicants submitted their ANDAs later in 2007. D.I. 2 ¶ 48.

III. ViroPharma's Serial Petitioning Conduct and Obstruction of FDA Approval of Generic Vancocin Capsules

Between March 2006 and April 2012, ViroPharma made at least 43 filings to the FDA and initiated three lawsuits against the FDA in federal court, all intended to obstruct and delay the FDA's approval of generic Vancocin Capsules, including: 24 citizen petition filings (including supplements and amendments) to the FDA; 17 public comments to the FDA regarding the FDA's in vitro dissolution guidance for generic Vancocin Capsules; a public comment to the FDA regarding the FDA's process for publishing bioequivalence guidelines; a supplemental New Drug Application ("sNDA") claiming three additional years of exclusivity for Vancocin Capsules; a lawsuit challenging the FDA's response to ViroPharma's Freedom of Information Act ("FOIA") requests; a lawsuit challenging the FDA's in vitro dissolution guidance for another generic drug referencing a branded drug that ViroPharma did not manufacture; and a lawsuit challenging the FDA's response to ViroPharma's citizen petition filings and approval of generic Vancocin Capsules. D.I. 2 ¶¶ 49, 118. ViroPharma knew that its petitioning campaign was unlikely to persuade the FDA to require clinical endpoint studies. Its consultants repeatedly told ViroPharma that it needed to provide supporting clinical data to have any chance of doing so, yet it submitted "filing after filing without any supporting clinical data." D.I. 2 ¶¶ 50–51.

Even though its own consultants believed ViroPharma's petitioning campaign was unlikely to succeed, ViroPharma continued to submit new filings because "its petitioning was obstructing and delaying the FDA's approval of generic Vancocin Capsules." D.I. 2 ¶¶ 53, 61. As one consultant explained, the FDA preferred to respond to citizen petition filings before, or contemporaneously with, approving an ANDA and that the ANDAs for generic Vancocin

Capsules appeared to be "in limbo" as a result of ViroPharma's petitioning. D.I. 2 ¶¶ 53, 61, 144. Another consultant told ViroPharma that clinical experts at the FDA appeared to have rejected its arguments, but that the pending decision on ViroPharma's citizen petition filings was "the only thing holding up final approval of a Vancocin [Capsules] generic." D.I. 2 ¶¶ 53, 68, 144.

Yet rather than provide supporting clinical data to persuade the FDA of its position, ViroPharma repeated arguments it had previously made, raised issues or arguments it could have raised earlier, submitted dubious filings, and made improper requests to the FDA. D.I. 2 ¶ 51.[3] Indeed, ViroPharma continued its petitioning campaign even after the independent Advisory Committee for Pharmaceutical Science, comprised of 16 experts, rejected its arguments and voted unanimously in favor of the FDA's in vitro dissolution guidance. D.I. 2 ¶¶ 51, 88, 101.

ViroPharma even stepped up its petitioning campaign as generic approval and entry approached. D.I. 2 ¶¶ 95–103. "Each time the FDA was close to finalizing its responses to ViroPharma's filings and contemporaneously approving generic Vancocin Capsules, ViroPharma would submit another filing." D.I. 2 ¶ 145. For example, just days before it anticipated generic entry, ViroPharma filed an sNDA claiming it was entitled to three more years of marketing exclusivity, during which the FDA could not approve generic Vancocin Capsules, despite internally considering its exclusivity claim a "long shot" and a "Hail Mary pass." D.I. 2 ¶¶ 96, 97. Absent ViroPharma's serial petitioning, the FDA would have approved generic Vancocin Capsules well before April 9, 2012, when it responded to and rejected ViroPharma's citizen petition filings, public comment filings, and sNDA exclusivity claim. D.I. 2 ¶ 147.

[3] *See, e.g.*, D.I. 2 ¶¶ 62 (failing to submit data), 64 (same), 66 (repeating issues), 75 (failing to submit supporting data and repeating issues), 76 (adding a new issue that could have been raised earlier and failing to include supporting data), 77 (failing to submit supporting data), 89 (repeating argument), 92 (failing to submit supporting data), 93–94 (submitting improper interrogatory-like questions to FDA), 101 (failing to submit supporting data).

ARGUMENT

I. Section 13(b) of the FTC Act Authorizes This Law Enforcement Action.

For more than 35 years, the FTC has brought cases in federal court to protect consumers under Section 13(b) of the FTC Act. During this period, courts have consistently held that the FTC may seek (1) a permanent injunction based on a defendant's past unlawful conduct if there is a likelihood that the unlawful conduct will recur and (2) monetary equitable relief (such as restitution or disgorgement) to remedy past violations even if there is no likelihood of recurrence. *See, e.g., FTC v. Evans Prods. Co.*, 775 F.2d 1084, 1087–88 (9th Cir. 1985).[4] No court has ever held that the FTC's authority to file suit is limited to cases of "ongoing or imminent" violations. And for good reason: ViroPharma's myopic reading of Section 13(b) would hamstring the agency and allow defendants to retain the fruits of their illegal activity simply because their unlawful activity ends before a lawsuit is filed. The Court should reject ViroPharma's invitation to adopt its unprecedented interpretation of Section 13(b).

In this case, the FTC has alleged that ViroPharma violated the FTC Act through its abuse of the FDA's citizen petition process and other sham petitioning activities, and that a cognizable danger exists that it will engage in similar activity in the future if not enjoined. The law requires no more at this stage in order to proceed in federal court. ViroPharma's fact-based arguments that its misconduct is not likely to recur can only be assessed on the evidence, not on the pleadings. And even if the Court were to conclude that ViroPharma's conduct is not likely to recur, the FTC could still seek monetary equitable relief.

[4] Courts have unanimously determined that this authorization for district courts to issue permanent injunctions carries with it the authority to issue monetary equitable relief such as restitution to injured consumers and disgorgement of unjust gains. *See, e.g., FTC v. Magazine Solutions, LLC*, 432 F. App'x 155, 158 n.2 (3d Cir. 2011).

A. The FTC may seek a permanent injunction based on a defendant's past conduct if it has reason to believe that unlawful conduct is likely to recur.

Before 1973, the FTC could enforce the FTC Act only through internal administrative court proceedings. In 1973, Congress concluded that additional enforcement mechanisms were necessary, and enacted Section 13(b).[5] Section 13(b) contains two distinct grants of authority. The first part of the statute authorizes the FTC to seek a *preliminary* injunction or temporary restraining order in federal court to stop ongoing or threatened conduct while the FTC conducts its own internal administrative trial.[6] The FTC may bring such an action whenever it finds "reason to believe" (1) that a defendant "is violating, or is about to violate" any provision of law enforced by the FTC, and (2) that "the enjoining thereof pending the issuance of a[n administrative] complaint by the Commission . . . would be in the public interest." 15 U.S.C. § 53(b). The Commission frequently uses this authority to seek preliminary injunctions against proposed mergers that may lessen competition but would likely consummate before the agency could complete its administrative adjudication.

Section 13(b), however, also contains a proviso that, "in proper cases," authorizes the FTC to seek, and the federal court to issue, a *permanent* injunction. This additional grant of authority is an "entirely different animal[]" from a preliminary injunction and is "governed by a separate statutory provision." *United States v. JS & A Grp., Inc.*, 716 F.2d 451, 456 (7th Cir. 1983). This proviso allows the FTC to litigate its entire case directly in federal court, rather than under its own administrative process, when it finds it more efficient to do so. *See FTC v. H.N.*

[5] The full text of Section 13(b) is attached hereto as Appendix A.

[6] The FTC's power to enforce violations of the FTC Act through its administrative process is granted under 15 U.S.C. § 45(b). In these administrative cases, trial is before an administrative law judge and then subject to *de novo* review by the full Commission, and review by a federal court of appeals. *Id.* If the Commission decides that the respondent has engaged in prohibited conduct, it may issue a cease and desist order, but cannot order monetary equitable relief. *Id*.

Singer, Inc., 668 F.2d 1107, 1110–11 (9th Cir. 1982). The FTC brought this case, like the majority of Section 13(b) cases, under this second authorization.

ViroPharma's argument that the FTC may file suit only in cases of "ongoing or imminent" violations hinges on the phrase "is violating, or is about to violate" in subdivision 13(b)(1). But clauses (b)(1) and (b)(2) both reside in the part of the statute addressed to preliminary injunctions, are joined by the conjunctive "and," and set off by dashes and indentation. Courts have consistently held that (b)(2) does not apply to cases brought under the permanent injunction proviso. *See JS & A Grp.*, 716 F.2d at 456; *Singer*, 668 F.2d at 1110–11; *FTC v. Commonwealth Mktg. Grp., Inc.*, 72 F. Supp. 2d 530, 535–36 (W.D. Pa. 1999); *see also* S. Rep. No. 93-151, at 30–31 (1973). That logic suggests equally that the "is violating, or is about to violate" clause in (b)(1) does not reach suits seeking permanent injunctions. *See FTC v. Va. Homes Mfg. Corp.*, 509 F. Supp. 51, 56 (D. Md. 1981) (noting in dicta that "[a] careful reading of § 13(b) lends some credence" to the view that the "'is . . . or is about to' language is not directed at the district court's power to grant permanent injunctions").

But even if this language did apply, Section 13(b) clearly authorizes this permanent injunction action. Courts have consistently treated the "is violating, or is about to violate" language in Section 13(b) as equivalent to the general standard for awarding injunctive relief set forth by the Supreme Court in *United States v. W.T. Grant Co.*, 345 U.S. 629 (1953). Thus, a court can issue an injunction based on a defendant's past violation of law if "there exists some cognizable danger of recurrent violation." *Id.* at 633. In *Evans Products*, for example, the Ninth Circuit held that, even where a defendant's violations "completely ceased" before the suit was filed, courts may issue an injunction if the wrongs are "ongoing *or likely to recur*." 775 F.2d at

1087–88 (emphasis added); *see also FTC v. Accusearch Inc.*, 570 F.3d 1187, 1201–02 (10th Cir. 2009) (holding that injunction was proper due to the cognizable danger of recurrence).

ViroPharma cites no case to support its novel contention that the "is violating or is about to violate" language of Section 13(b)(1) requires that an FTC suit for a permanent injunction allege an "ongoing" or "imminent" violation of law. We are aware of none. In every decision ViroPharma cites, the conduct had stopped before the suit was filed and the court assessed whether to award a preliminary injunction based on a "likelihood of recurrence" standard. Indeed, ViroPharma quotes language from *Evans Products* stating that injunctive relief can be based on past violations that are "likely to recur." D.I. 20 at 14. In the other cases ViroPharma cites, the courts found only that the FTC could not obtain a preliminary injunction because it had failed to prove a likelihood of recurrence. *See, e.g.*, *FTC v. Home Assure, LLC*, No. 8:09-cv-547-T-23TBM, 2009 WL 1043956, at *20 (M.D. Fla. Apr. 16, 2009) (denying preliminary injunction because, on the record presented, the court was "unable to find that there is a cognizable danger of recurrent violation or some reasonable likelihood of future violations"); *FTC v. Merch. Servs. Direct, LLC*, No. 13-CV-2079-TOR, 2013 WL 4094394, at *3 (E.D. Wash. Aug. 13, 2013) (addressing whether the FTC had made a "proper showing" to obtain a preliminary injunction, which "necessarily requires the FTC to demonstrate that the violations referenced in its Complaint are likely to recur").

Courts considering motions to dismiss in 13(b) cases have likewise treated "is violating or is about to violate" as synonymous with a "likelihood of recurrence" inquiry. For example, in *FTC v. Engage-A-Car Services, Inc.*, the defendants sought dismissal on the ground that the FTC "failed to allege that [either defendant] is violating or is about to violate any law enforced by the FTC in accordance with Section 13(b)." No. 86-2578, 1986 WL 15066, at *1 (D.N.J. Dec. 18,

1986). The court denied the motion, finding the facts pleaded would support an inference that the defendants' violations "are likely to recur." *Id*. at *5; *see also FTC v. Citigroup Inc*., 239 F. Supp. 2d 1302, 1305–06 (N.D. Ga. 2001) (denying motion to dismiss for lack of jurisdiction under Section 13(b) where complaint sufficiently alleged a likelihood of future violations).

Although the Third Circuit has not addressed the meaning of the "is violating, or is about to violate" language in Section 13(b) of the FTC Act, it has addressed comparable language that appears in the SEC statutes.[7] In *SEC v. Bonastia*, 614 F.2d 908, 912 (3d Cir. 1980), the court noted that SEC statutes permit the agency to sue "whenever it appears to the commission that a person is engaged in acts in violation of the securities laws." *Id.* It then explained that the standard to determine if an injunction should issue was "based on a determination of whether there is a reasonable likelihood that the defendant, if not enjoined, will again engage in the illegal conduct." *Id.*; *see also SEC v. Commonwealth Chem. Secs. Inc.*, 574 F.2d 90, 99 (2nd Cir. 1978) (Friendly, J.) (holding that "the ultimate test is whether the defendant's past conduct indicates . . . that there is a reasonable likelihood of further violation in the future.").

The consistent approach in the case law is not surprising. First, ViroPharma's interpretation of Section 13(b)'s permanent injunction proviso makes no sense. As one court explained, such an interpretation "would be illogical because this would create situations when the [agency] has made a showing that it can obtain injunctive relief but does not have standing to sue for such relief." *SEC v. Richie*, No. EDCV 06-63-VAP-SFLX, 2008 WL 2938678, at *9

[7] *See* 15 U.S.C. § 77t(b) (authorizing SEC to sue "[w]henever it shall appear to the Commission that any person is engaged or about to engage in any acts or practices which constitute or will constitute a violation" of the Securities Act), § 78u(d)(1) (authorizing SEC to sue "[w]henever it shall appear to the Commission that any person is engaged or about to engage in acts or practices constituting a violation" of the Exchange Act).

(C.D. Cal. May 9, 2008). Such an anomalous result is inconsistent with any logical construction of the FTC's authority.

Second, imposing an "ongoing" or "imminent" requirement to the FTC's permanent injunction authority would impede effective and efficient law enforcement, encouraging targets of FTC investigations seeking to evade a suit under Section 13(b) to prolong the investigation until their unlawful conduct is completed. And ViroPharma's theory would have drastic implications for the FTC's efforts to secure effective relief for consumers injured by anticompetitive, unfair, or deceptive practices. For example, it would likely have precluded the FTC's recent settlement with Volkswagen over its false and deceptive "Clean Diesel" advertising campaign, which included a permanent injunction to protect consumers from similar future conduct and $11.2 billion in consumer restitution.[8]

In sum, ViroPharma's assertion that the FTC can invoke Section 13(b) "only in limited circumstances where there is a need for immediate relief" (D.I. 20 at 2) conflicts with over three decades of case law interpreting the statute's permanent injunction proviso, defies logic, and undermines the congressional goal of efficient and effective enforcement underlying the proviso.

B. The FTC has adequately alleged a likelihood of recurrence.

ViroPharma's assertion that the FTC's suit brought under the permanent injunction proviso should be dismissed for failure to plead a plausible claim for injunctive relief rests on two basic legal errors.

First, as the Third Circuit made clear in *Bonastia*, the *W.T. Grant* inquiry is a fact-specific analysis, requiring the district court to consider "the totality of the circumstances" regarding the violation and the violator. 614 F.2d at 912. Here, the FTC's Complaint contains

[8] *See* Complaint, *FTC v. Volkswagen Grp. of America, Inc.*, No. 3:16-cv-01534 (N.D. Cal. Mar. 29, 2016).

extensive well-pleaded factual allegations that address factors essential to a proper *W.T. Grant* inquiry. It amply sets forth a claim for injunctive relief that is "plausible on its face." *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). In contending otherwise, ViroPharma simply treats factual allegations reflecting the protracted, deliberate, and egregious nature of its conduct—and the ensuing consumer harm—as irrelevant. In so doing, it invites the Court to commit legal error.

Second, ViroPharma's argument rests on its own "spin" on the facts, and disregards the fundamental canon governing motions to dismiss: the court must draw all reasonable inferences from well-pleaded factual allegations in the plaintiff's favor. *See, e.g., Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 231–33 (3d Cir. 2008). Here, ViroPharma asks this Court to do precisely the opposite.

1. ViroPharma ignores factors essential to a proper inquiry into the likelihood of recurrence.

In *Bonastia*, the Third Circuit explained that, at the relief stage, various factors must be considered in determining whether there is a "reasonable likelihood" that the defendants, if not enjoined, will again engage in illegal conduct. 614 F.2d at 912. The court stated that once a violation is proven, "a court makes a prediction of the likelihood of future violations based on . . . the totality of the circumstances surrounding the particular defendant and the past violations that were committed." *Id.* The court specified consideration of, "among other things, the degree of scienter involved on the part of the defendant, the isolated or recurrent nature of the infraction, the defendant's recognition of the wrongful nature of his conduct, the sincerity of his assurances against future violations, and the likelihood, because of defendant's professional occupation, that future violations might occur." *Id.* The district court's failure to consider "factors that are essential to a proper determination" rendered its denial of an injunction an abuse of discretion.

Id. at 913. That is, "the repetitiveness of the violations weighs heavily in favor of the imposition of an injunction." *Id.* Courts in Section 13(b) cases undertake the same multi-factor approach when deciding whether to grant permanent injunctive relief. *See, e.g.*, *FTC v. Minuteman Press*, 53 F. Supp. 2d 248, 260–61 (E.D.N.Y. 1998); *FTC v. Magui Publishers, Inc.*, No. 89-cv-3818, 1991 WL 90895, at *15 (C.D. Cal. Mar. 28, 1991).

The FTC's 45-page Complaint contains numerous detailed factual allegations that relate to these various factors. As to scienter, the Complaint contains extensive factual allegations supporting the inference that ViroPharma acted with knowledge that its repeated filings amounted to an unprecedented abuse of the FDA's citizen petition process. D.I. 2 ¶¶ 46, 50–51, 53, 57–59, 61, 97, 144. ViroPharma's campaign to obstruct and delay generic competition through repeated baseless filings was not an isolated incident; it was conducted over the course of six years and involved at least 43 submissions to the FDA and three federal court lawsuits against the FDA. D.I. 2 ¶¶ 49, 118. ViroPharma's unlawful conduct, which obstructed and delayed entry of a lower-cost generic version of Vancocin Capsules for at least 21 months, resulted in consumer harm estimated at hundreds of millions of dollars. D.I. 2 ¶¶ 1, 149. And, ViroPharma is currently positioned to commit further violations as the company continues to develop, manufacture, and market branded pharmaceutical products. D.I. 2 ¶¶ 8, 150–51. Moreover, ViroPharma has expressed no recognition of culpability and asserts that its conduct was merely an exercise of its First Amendment rights. D.I. 20 at 20. The "totality of the circumstances" alleged here gives rise to an inference of a cognizable danger of similar unlawful conduct in the future.

Thus, well-pleaded factual allegations—supporting all of the factors that courts must assess when deciding whether to *grant* injunctive relief—show that the FTC has plausibly

alleged a claim for permanent injunctive relief. ViroPharma's assertion that the FTC Complaint contains no more than "conclusory" allegations and "formulaic recitations" ignores factual allegations addressing factors that the Third Circuit recognizes are "essential to a proper determination." *See Bonastia*, 614 F.2d at 913. To be sure, the mere *existence* of some past violation does not standing alone justify injunctive relief. But, as *Bonastia* and other cases make clear, any assessment of the need for a prospective remedy for a past violation cannot ignore facts about the nature and character of that violation or the public harm inflicted. ViroPharma's attempt to dismiss the relevance of allegations detailing the company's intentional and egregious misuse of government processes to obstruct and delay competition is wrong as a matter of law.

2. ViroPharma's factual arguments cannot be resolved on a motion to dismiss.

Because the *W.T. Grant* inquiry turns on inferences about future conduct drawn from a variety of factual considerations, including facts about the substantive violation, it is particularly ill-suited to resolution on a motion to dismiss. As one district court observed, "even a cursory review of these factors [relevant to the likelihood of future violations] makes apparent the impossibility of determining the likelihood of a future violation at the outset of the litigation." *SEC v. Jackson*, 908 F. Supp. 2d 834, 874 (S.D. Tex. 2012). Similarly, in reversing dismissal of a government claim for injunctive relief, the Second Circuit termed it "most unusual to dismiss a prayer for injunctive relief at this preliminary stage of the litigation," given the complaint's plausible allegations that defendants intentionally violated the law. *SEC v. Gabelli*, 653 F.3d 49, 61 (2d Cir. 2011), *rev'd on other grounds*, 568 U.S. 442 (2013). ViroPharma's request that the Court decide that no likelihood of recurrence exists at this nascent stage of the litigation is contrary to law for several reasons.

First, ViroPharma erroneously conflates the analysis governing claims for injunctive relief by private plaintiffs with that applied in a government law enforcement suit. It cites no case dismissing a Section 13(b) permanent injunction suit for failure to plead a plausible claim for permanent injunctive relief, relying instead on cases brought by private plaintiffs. But unlike government law enforcers, private plaintiffs bear a threshold burden to plead irreparable injury to establish their standing and must ultimately prove irreparable injury to obtain injunctive relief.[9] Indeed, in the antitrust context, the distinction between government law enforcement and private suits is particularly well-established.[10]

Moreover, ViroPharma's contention that there is no likelihood of recurrence because generic versions of Vancocin Capsules are now on the market fails as a matter of law. The concern in a government enforcement suit about recurrent violations is not limited to repetition of exactly the same conduct, but rather with related violations of the same type. *See, e.g.*, *Nat'l Soc'y of Prof'l Eng'rs v. United States*, 435 U.S. 679, 697 (1978) (stating that antitrust remedies are not limited to "a simple proscription against the precise conduct previously pursued").[11]

Finally, the other reasons ViroPharma proffers for its contention that no likelihood of recurrence is present here run squarely into the rule that at the motion to dismiss stage, all

[9] *See, e.g.*, *City of Los Angeles v. Lyons*, 461 U.S. 95, 108–10 (1983) (private plaintiff lacked standing to seek injunctive relief absent a real and immediate threat of future injury); *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 301–02 (2012) (private antitrust plaintiffs could not demonstrate the requisite likelihood of future injury to confer standing to seek injunctive relief); *see also* D.I. 20 at 15–16 (citing *In re Plavix Indirect Purchaser Antitrust Litig*., No. 1:06-cv-226, 2011 WL 335034, at *4 (S.D. Ohio Jan. 31, 2011) (private party failed to establish standing to seek injunctive relief)).

[10] *F. Hoffman-La Roche Ltd. v. Empagran S.A.*, 542 U.S. 155, 170–71 (2004); *see also* IIA Areeda & Hovenkamp, ANTITRUST LAW at ¶¶ 303a, 303e (noting public interest purposes and scope of remedies distinctions between private and government suits).

[11] ViroPharma does not contend that entry of generic Vancocin Capsules renders this case moot, nor could it plausibly do so. *See, e.g., Chafin v. Chafin*, 133 S. Ct. 1017, 1023 (2013) (a case is moot "only when it is impossible for a court to grant any effectual relief whatever to the prevailing party") (quotations omitted).

inferences are drawn in the plaintiff's favor. *See, e.g.*, *FTC v. Amazon.com, Inc.*, 71 F. Supp. 3d 1158, 1168 (W.D. Wash. 2014) (denying motion to dismiss and noting that the question of whether Amazon had fully cured its alleged unfair practices "is a question of fact not properly resolved on a motion to dismiss"). ViroPharma's contention that there is no likelihood of a recurrent violation here fails for the same reason.

For example, ViroPharma points to its 2014 acquisition by Shire. D.I. 20 at 17. But whether ViroPharma's presence in the Shire corporate structure makes a recurrent violation unlikely is precisely the type of factual issue that would be inappropriate to resolve on a motion to dismiss. Similarly, ViroPharma incorrectly argues that Section 505(q) of the 2007 amendments to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(q), eliminated the possibility that a future ViroPharma sham citizen petition could delay approval of a generic drug. According to ViroPharma, "[b]y virtue of these 2007 amendments, any citizen petition that ViroPharma might file in the future would not and could not pose a cognizable threat of improperly delaying generic approval." D.I. 20 at 18.[12] The FDA reports on which ViroPharma relies, however, (D.I. 20 at 18-19) confirm that, despite the 2007 amendments, citizen petitions are still causing delays:

> [T]he agency is concerned that section 505(q) may not be discouraging the submission of petitions that do not raise valid scientific issues and are intended primarily to delay the approval of competitive drug products. We also believe that innovator companies may be implementing strategies to file serial 505(q) petitions and petitions for reconsideration in an effort to delay approval of ANDAs . . . for competing drugs.[13]

[12] Section 505(q) applies only to citizen petitions filed in September 2007 or later. *See* Food & Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2007) (enacted on Sept. 27, 2007). ViroPharma's first citizen petition was filed in March 2006, D.I. 2 ¶ 54, and ViroPharma does not argue that Section 505(q) applies to any of the past conduct alleged in the Complaint.

[13] FDA 2010 Report (D.I. 21 at 114) at 5; *see also, e.g.*, FDA 2011 Report (D.I. 21 at 121) at 6; FDA 2012 Report (D.I. 21 at 129) at 7; FDA 2013 Report (D.I. 21 at 137) at 7; FDA 2014 Report (D.I. 21 at 148) at 10.

The FDA also reported to Congress that Section 505(q)'s provision authorizing FDA to summarily deny meritless petitions designed primarily to delay approval of a competitive drug had "neither curbed the filing of frivolous petitions submitted with the primary purpose of delay, nor has it permitted FDA to dispose of such petitions without expending substantial amounts of resources." FDA 2013 Report (D.I. 21 at 137) at 7. If anything, ViroPharma itself has inserted issues of fact into its motion to dismiss.

ViroPharma is thus left with the argument that the number of citizen petitions that the FDA did not respond to within the Section 505(q) timeframe is small. D.I. 20 at 19. But the number of times that the FDA was unable to respond to a citizen petition within the § 505(q) timeframe is irrelevant to assessing whether the FTC has adequately alleged that the nature and character of ViroPharma's alleged violation poses a cognizable risk of future harm. The FDA reports cannot—and do not—provide any basis to find that Section 505(q) has eliminated the risk that similar abuse of the citizen petition process in the future could delay a generic drug's approval. ViroPharma cites no case law supporting its argument. To the contrary, *In re Suboxone Antitrust Litig.*, 64 F. Supp. 3d 665, 690–91 (E.D. Pa. 2014), held that allegations of delay due to a sham citizen petition remained plausible even after the enactment of Section 505(q).

Finally, ViroPharma's argument that a "lack of any specificity in the FTC's prayer for relief confirms that the FTC has failed to plead the existence of a specific violation that is 'about to' happen" is meritless. D.I. 20 at 19. Rule 8(a)(3) "does not require that the demand for judgment be pled with great specificity." *Sheet Metal Workers Local 19 v. Keystone Heating & Air Cond.*, 934 F.2d 35, 40 (3d Cir. 1991). "[A]ny concise statement identifying the remedies and the parties against whom relief is sought will be sufficient." Wright & Miller, 5 FED. PRAC. & PROC. CIV. § 1255 (3d ed.) (footnotes omitted). "[T]he demand is not itself a part of the

plaintiff's claim, and so failure to specify relief to which the plaintiff was entitled would not warrant dismissal under Rule 12(b)(6)." *Bontkowski v. Smith*, 305 F.3d 757, 762 (7th Cir. 2002) (citations omitted). Rule 54(c), which provides that a prevailing party may obtain any relief to which he is entitled even if he "has not demanded such relief in [his] pleadings," dispels any doubt on this question. *Id.*

In any event, ViroPharma's concerns about the scope of an injunction are ill-founded and premature. *See Amazon.com*, 71 F. Supp. 3d at 1168 ("the specific terms of an injunction would be more properly resolved if necessary at the conclusion of litigation"). Nor is there merit to ViroPharma's concern that any injunction would constitute an unlawful prior restraint of speech. D.I. 20 at 20 & n.18. After the evidence has been presented, the court may exercise its equitable "power to fashion any remedy deemed necessary and appropriate to do justice in the particular case." *United States v. Price*, 688 F.2d 204, 211 (3d Cir. 1982).

C. Even without a likelihood of recurrence, the FTC can proceed in federal court to obtain other equitable relief, such as restitution and disgorgement.

The FTC is not limited to seeking injunctive relief under Section 13(b). "While the provision's express text refers only to injunctive relief, courts have consistently held that the unqualified grant of statutory authority to issue an injunction under Section 13(b) carries with it the full range of equitable remedies, including the power to grant consumer redress and compel disgorgement of profits." *FTC v. Bronson Partners, LLC*, 654 F.3d 359, 365 (2d Cir. 2011) (quotations omitted) (collecting cases); *see also Magazine Solutions*, 432 F. App'x at 158 & n.2 (recognizing court's authority to grant monetary equitable relief); *FTC v. Check Invs., Inc.*, 502 F.3d 159, 162 (3d Cir. 2007) (affirming $10.2 million FTC restitution award).[14]

[14] The Supreme Court has repeatedly held that the grant of authority to issue an injunction vests the court with the full scope of equity jurisdiction absent a "clear and valid" legislative command to the contrary. *Porter v. Warner Holding Co.*, 328 U.S. 395, 398 (1946); *see also Mitchell v.*

Courts have also uniformly held that the FTC may proceed in federal court to obtain these other forms of equitable relief even when the conduct at issue has concluded and is not likely to recur. This principle is illustrated by the very cases ViroPharma cites. In each case—*Evans Products*, *Home Assure*, and *Merchant Services Direct*—the defendants' conduct had ceased before the FTC filed suit. In each case, the court denied a preliminary injunction because it could not find a likelihood of recurrence on the record before it. But none of those courts dismissed the FTC's case, instead allowing the FTC to continue to seek other forms of equitable relief. *See Evans Prods.*, 775 F.2d at 1088 ("Courts have inherent equitable powers to grant ancillary relief, other than a preliminary injunction restraining future violations of the law, when there is no likelihood of recurrence."); *In re Evans Prods. Co.*, 60 B.R. 863, 869 (S.D. Fla. 1986) (recognizing that FTC federal court enforcement claim was still viable although "the violations have ceased and are not likely to recur"); *Home Assure*, 2009 WL 1043956, at *20 (granting asset freeze in support of future monetary remedies notwithstanding finding of no "cognizable danger of recurrent violation or some reasonable likelihood of future violations"); *Merch. Servs. Direct*, 2013 WL 4094394, at *3 ("[I]f the FTC fails to establish that past violations are likely to recur, the only relevant consideration is whether 'ancillary' relief in the form of an asset freeze and/or the appointment of a receiver is necessary to preserve effective relief for injured consumers."). These outcomes make sense because even when the unlawful conduct has ceased, the defendant continues to benefit from its prior activity.

A recent district court decision addressed this issue even more directly. In *FTC v. LeanSpa, LLC*, the defendant had gone out of business over a month before the FTC filed its

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Robert De Mario Jewelry, Inc., 361 U.S. 288, 291–92 (1960); *United States v. Moore*, 340 U.S. 616, 619 (1951). The Third Circuit relied on these cases in *United States v. Lane Labs-USA Inc.*, 427 F.3d 219, 220 (3d Cir. 2005) (holding that provision of the Food, Drug and Cosmetic Act authorizing courts to grant injunctive relief also allowed courts to award restitution).

Complaint, and moved to dismiss, arguing that the FTC's action was "not a proper case because there is no prospect that it will operate in the future and, as a result, the FTC would be unable to obtain a permanent injunction." No. 3:11-CV-1715, 2015 WL 1004240, at *16 (D. Conn. March 5, 2015) (quotations omitted), *aff'd in relevant part sub nom., FTC v. LeadClick Media, LLC*, 838 F.3d 158 (2d Cir. 2016). The district court rejected this argument, holding that "'courts have inherent equitable powers to grant ancillary relief when there is no likelihood of recurrence.'" *Id*. (quoting *Evans Prods.*, 775 F.2d at 1088). "Because Section 13(b) carries with it the full range of equitable remedies, the FTC can obtain monetary relief regardless of the absence of a permanent injunction." *Id.* (citations and quotations omitted).[15]

ViroPharma fails to cite a single decision dismissing an FTC action because a defendant's conduct had concluded and there was no likelihood of recurrence, and we are aware of no such case. Thus, even if there were no cognizable danger that ViroPharma's unlawful conduct could recur, the FTC's case could still proceed to seek other forms of equitable relief.

II. The Complaint Adequately Alleges that ViroPharma Engaged in Sham Petitioning Not Protected by the *Noerr-Pennington* Doctrine.

While the *Noerr-Pennington* doctrine protects genuine petitioning activity directed towards governmental processes from antitrust liability, it does not protect petitioning that is a "mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor." *E.R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961). "The 'sham' exception to *Noerr* encompasses situations in which persons use the governmental *process*—as opposed to the *outcome* of that process—as an anticompetitive weapon." *City of Columbia v. Omni Outdoor Advert., Inc.*, 499 U.S. 365, 380

[15] Courts have reached a similar conclusion in SEC enforcement actions. *See, e.g., SEC v. Unifund SAL*, 910 F.2d 1028 (2d Cir. 1990) (holding that SEC had not made requisite showing of likelihood of recurrence to obtain an injunction, but that it could obtain an asset freeze and seek other equitable relief).

(1991). In cases involving a single sham filing, the inquiry first asks whether the petition was objectively baseless. *Prof'l Real Estate Invs., Inc. v. Columbia Pictures Indus.*, 508 U.S. 49, 60–61 (1993). But when a complaint alleges serial filings, the standard from *California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508 (1972), governs. *See Hanover 3201 Realty, LLC v. Village Supermarkets, Inc.*, 806 F.3d 162, 180 (3d Cir. 2015). The *California Motor* "inquiry asks whether a series of petitions were filed with or without regard to merit and for the purpose of using the government process (as opposed to the outcome of that process) to harm a market rival and restrain trade." *Id.*[16]

In this case, because the Complaint alleges that ViroPharma engaged in serial petitioning by making 46 successive and meritless filings over the course of six years, the *California Motor* standard applies. Under that standard, the Complaint pleads factual allegations that ViroPharma's petitioning was undertaken without regard to merit and to obstruct and delay FDA approval of generic Vancocin Capsules. But even if the standard for a single sham petition articulated in *Professional Real Estate* applied, the FTC has adequately alleged that ViroPharma's sham petitions were objectively baseless.

A. *Noerr-Pennington* issues are not ripe for consideration on a motion to dismiss.

At the threshold, a motion to dismiss is an imperfect vehicle to consider whether *Noerr-Pennington* protects specific petitioning activity, for whether petitioning activity is sham is

[16] The *California Motor* standard used in a case involving a pattern of filings, like this one, is more flexible than that in a single-petition case. That is because "[n]ot only do pattern cases often involve more complex fact sets and a greater risk of antitrust harm, but the reviewing court sits in a much better position to assess whether a defendant has misused the governmental process to curtail competition." *Hanover 3201 Realty*, 806 F.3d at 180; *see also* Federal Trade Commission, ENFORCEMENT PERSPECTIVES ON THE NOERR-PENNINGTON DOCTRINE: AN FTC STAFF REPORT (2008) (noting that "sound policy reasons support treating repetitive use of the government process differently from single lawsuits").

generally a question of fact and not amenable to resolution at the pleading stage.[17] As more fully explained below, the FTC has adequately alleged the elements of its sham petitioning claims against ViroPharma. To the extent ViroPharma disagrees, those disagreements are factual disputes not subject to resolution on a motion to dismiss.

B. ViroPharma's 46 filings to the FDA and courts constitute a pattern or series of petitioning.

The Third Circuit has not established a rigid "minimum number requirement" for determining how many sham petitions constitute a pattern sufficient to trigger the *California Motor* standard. *Hanover 3201 Realty*, 806 F.3d at 181. The Third Circuit, however, has held that four petitions may constitute a pattern where the defendant "filed these sham proceedings at every opportunity to obstruct [the rival firm] from obtaining all necessary government approvals." *Id.* (quotations omitted). Here, the FTC has alleged in detail ViroPharma's 46 successive and meritless filings to the FDA and the courts to obstruct and delay approval of generic Vancocin Capsules. D.I. 2 ¶¶ 1, 49–118. According to the Complaint, ViroPharma's serial and meritless petitioning spanned six years, with four filings in 2006, four more in 2007, an additional five filings in 2008, sixteen filings in 2009, twelve filings in 2010, four more in 2011, and a final filing in 2012. D.I. 2 ¶ 118.

[17] See *Otsuka Pharm. Co. v. Torrent Pharms. Ltd.*, 118 F. Supp. 3d 646, 657 (D.N.J. 2015) (denying a motion to dismiss because determinations related to baselessness and intent of the petitioning "require inquiry into issues of fact, which cannot be resolved in the context of a motion to dismiss."); *Suboxone*, 64 F. Supp. 3d at 689 (denying a motion to dismiss a sham citizen petition claim and noting that "[w]hether petitioning activity is a sham is generally a question for the jury"); *In re Prograf Antitrust Litig.*, No. 11-2242, 2012 WL 293850, at *6 (D. Mass. Feb. 1, 2012) (denying a motion to dismiss a sham citizen petition complaint and holding that determining whether a citizen petition is sham "is only proper at this early stage when no facts are contested"); *Shionogi Pharma, Inc. v. Mylan, Inc.*, No. 10-1077, 2011 WL 3860680, at *6–7 (D. Del. Aug. 31, 2011) (denying motion to dismiss because questions of fact related to intent to delay FDA approval of ANDA through sham litigation required resolution of questions of fact).

Faced with such detailed allegations, ViroPharma raises factual issues about the proper way to tally the number of petitions. For example, ViroPharma argues that its 24 citizen petition filings should not be counted separately. D.I. 20 at 27. But the Complaint adequately alleges that they are separate filings: A citizen petition is a request to the FDA for an action or actions and each supplement or amendment filed can similarly ask for an additional FDA action or actions. D.I. 2 ¶ 18. ViroPharma amended and supplemented its original citizen petition 23 times.[18] The Complaint alleges that the FDA reviews, resolves, and responds to each citizen petition filing, regardless of whether it is labeled a citizen petition, amendment, or supplement before or at the same time the FDA approves a generic application. D.I. 2 ¶ 20.

ViroPharma expends a great deal of effort arguing that citizen petition supplements and amendments are comparable to filings in a lawsuit, D.I. 20 at 27, but the analogy fails. In a lawsuit, the rules of civil procedure govern the number, type, content, and timing of filings. For example, Rule 15 dictates that a party may amend its complaint once as a matter of right (with certain timing constraints), or with leave of the court or the opposing party's consent.[19] No such rules applied to ViroPharma's citizen petition and public docket filings, and the Complaint alleges that ViroPharma took advantage of its ability to flood the FDA with frivolous, meritless filings, amending and supplementing its citizen petition claims and requests in 23 instances.

Even assuming *arguendo* that ViroPharma's 24 citizen petition filings constitute a single petition, the Complaint contains detailed allegations that ViroPharma initiated or submitted filings in other proceedings before or against the FDA. These 22 other filings were lodged in six

[18] D.I. 2 ¶¶ 55, 58, 62–63, 65, 66, 69, 75, 77, 79, 83, 89, 94, 98, 100, 103.
[19] ViroPharma sets forth a classic strawman argument by mischaracterizing the FTC's approach to suggest that the multiple docket entries in *Professional Real Estate* related to a single lawsuit would count as separate entries. As explained above, lawsuits and citizen petition filings are dissimilar and not subject to the same treatment for *Noerr-Pennington* purposes.

proceedings distinct from ViroPharma's citizen petition docket: (1) the docket for the FDA's in vitro dissolution guidance for generic Vancocin Capsule[20]; (2) the docket for FDA's guidance regarding its process for publishing bioequivalence guidance; (3) an sNDA for Vancocin Capsule; (4) ViroPharma's FOIA lawsuit against the FDA; (5) ViroPharma's lawsuit against the FDA challenging in vitro dissolution guidance for another generic drug; and (6) ViroPharma's lawsuit challenging FDA's denial of ViroPharma's citizen petition and approval of generic Vancocin Capsules. D.I. 2 ¶¶ 49, 118.

ViroPharma argues that its other proceedings should not count because they could not have harmed the competitive process. D.I. 20 at 28–29. However, the Complaint alleges that ViroPharma's public comments, sNDA, and lawsuits not only could—but did—harm the competitive process. D.I. 2 ¶¶ 144, 147–49. As detailed in the Complaint, ViroPharma's strategically timed filings, including citizen petition filings, public comment filings,[21] the sNDA, and lawsuits, impeded the FDA's response to ViroPharma's claims and approval of generic Vancocin Capsules. D.I. 2 ¶¶ 1, 53, 68, 128, 144.

ViroPharma also ignores the FTC's allegations when it argues that the earliest an ANDA was ready for approval was July 2010 and suggests its filings submitted before July 2010 should not count and must have had merit. But the FTC's Complaint alleges that "generic entry likely would have occurred *by* July 2010—when Akorn's ANDA was otherwise ready for approval—

[20] ViroPharma argues that the Complaint double counts by tallying citizen petition filings and filings to the FDA's public comment docket separately. But the Complaint plausibly alleges that these are separate dockets; therefore, the issue is a question of fact that cannot be resolved on a motion to dismiss.

[21] ViroPharma also suggests that its public comments should not count because the FDA "invited public comment for sixty days." D.I. 20 at 2, 28. But sham petitioning cannot be protected merely because the government permits or provides a public forum for petitioning. Moreover, *Hanover 3201 Realty* holds that a "holistic review" of a defendant's activities is appropriate, and ViroPharma's attempt to parse out portions of its scheme is precluded.

or even earlier." D.I. 20 at 29 (citing D.I. 2 ¶ 147) (emphasis added)). ViroPharma ignores the allegation that approval could have come "even earlier" than July 2010 if not for ViroPharma's filings. D.I. 2 ¶¶ 60, 145, 147.

C. The Complaint adequately alleges that ViroPharma's serial petitioning constitutes sham petitioning under the *California Motor* standard.

When a party alleges a series of petitioning, the sham litigation standard from *California Motor* applies, not the standard from *Professional Real Estate*. *See Hanover 3201 Realty*, 806 F.3d at 180. *See also Waugh Chapel S., LLC v. United Food & Commercial Workers Union Local 27*, 728 F.3d 354, 363–64 (4th Cir. 2013); *Primetime 24 Joint Venture v. Nat'l Broad. Co.*, 219 F.3d 92, 101 (2d Cir. 2000); *USS-POSCO Indus. v. Contra Costa Cnty. Bldg. & Const. Trades Council, AFL-CIO*, 31 F.3d 800, 810–11 (9th Cir. 1994). "Thus, when faced with a series or pattern of lawsuits, the question is not whether any one of them has merit—some may turn out to, just as a matter of chance." *Hanover 3201 Realty*, 806 F.3d at 180 (quotations omitted). Instead, the "inquiry asks whether a series of petitions were filed with or without regard to merit and for the purpose of using the governmental process (as opposed to the outcome of that process) to harm a market rival and restrain trade." *Id*. "[A] court should perform a holistic review that *may* include looking at the defendant's filing success . . . as circumstantial evidence of the defendant's subjective motivations." *Id*. (emphasis added). Accordingly, a lack of success "will tend to support a finding that the filings were not brought to address any actual grievances." *Id*. at 181. Besides win-loss percentage, "[c]ourts should also consider other evidence of bad-faith." *Id*.

ViroPharma's filings were not successful. ViroPharma's purported objective was to convince the FDA to require generic applicants to conduct clinical endpoint studies, and it ultimately failed to convince the FDA to do so. D.I. 20 at 24. The FDA concluded that

ViroPharma's scientific arguments were "unsupported" and "lack merit." D.I. 2 ¶¶ 1, 104, 122. Nor were any of ViroPharma's other petitions successful. The FDA denied ViroPharma's sNDA claim that it was entitled to a three-year marketing exclusivity for Vancocin Capsules. D.I. 2 ¶¶ 103, 107, 124. Courts dismissed two of ViroPharma's three lawsuits against the FDA, and ViroPharma withdrew the third. D.I. 2 ¶¶ 109,125.

Contrary to ViroPharma's argument (D.I. 20 at 26), serial petitioning can be a sham even when a small number of the filings turn out to have some merit as "even a broken clock is right twice a day." *Hanover 3201 Realty*, 806 F.3d at 180 (quoting *USS-POSCO*, 31 F.3d at 811). As the Complaint alleges, to the extent ViroPharma had any limited success at all, it related to the publication and elaboration of the FDA's in vitro dissolution for generic Vancocin Capsule in December 2008. D.I. 2 ¶ 121. As the Third Circuit stated, "hitting a single in the second inning" does not preclude a finding that a series of filings were a sham. *Hanover 3201 Realty,* 806 F.3d at 182.

Besides alleging ViroPharma's anemic success rate, the Complaint contains detailed allegations supporting the inference that ViroPharma acted in bad faith. Conduct demonstrating bad faith may include, for example, amending filings with facts and arguments known to the defendant earlier, submitting arguments the defendant doubted, and having consultants "tout" the ability to delay the government approval process. *See id.* at 181–83. Here, consultants told ViroPharma that its citizen petition filings were unlikely to succeed on the merits, particularly absent supporting clinical data, but concurrently were slowing down the generic approval process and standing as the last hurdle to generic approval. D.I. 2 ¶¶ 46, 53, 57. According to the Complaint, ViroPharma: strategized about using citizen petition filings to extend exclusivity for existing drugs (D.I. 2 ¶ 67); submitted dubious arguments and filings, rather than the data it

knew was needed in support of its filings (D.I. 2 ¶¶ 83, 86, 87, 97–98, 101–02); claimed that the FDA had not originally approved Vancocin Capsules based on in vitro dissolution studies despite internal documents to the contrary (D.I. 2 ¶ 83*);* submitted filings it analyzed internally as a "long shot" and a "Hail Mary pass" (D.I. 2 ¶¶ 51, 97); withheld information from the FDA that it had agreed to provide (D.I. 2 ¶¶ 62, 77); and delayed making arguments and filings until right before anticipated decision points (D.I. 2 ¶¶ 67, 145). In short, the Complaint adequately alleges that ViroPharma's petitioning was, as the FDA noted with regard to certain of its petitioning tactics, "an improper use of the citizen petition process." D.I. 2 ¶¶ 51, 93, 98, 106.

D. Even if *Professional Real Estate* applied, the Complaint adequately alleges that ViroPharma's petitioning was objectively baseless.

Even if *Professional Real Estate* applied here—which it does not—the Complaint sufficiently alleges that ViroPharma's petitioning was objectively baseless. *Professional Real Estate* outlined a two-step inquiry for evaluating whether a single suit or legal proceeding constitutes a sham: (1) "the lawsuit must be objectively baseless" and (2) "the baseless lawsuit conceals an attempt to interfere directly with the business relationships of a competitor through the use [of] the governmental process . . . as an anticompetitive weapon." 508 U.S. at 60–61 (citations and quotations omitted).[22]

ViroPharma argues that failing to include the phrase "objectively baseless" in the Complaint "should be dispositive at the pleading stage." D.I. 20 at 24. This argument is not only overly formalistic, it is wrong and ignores the gravamen of the FTC's allegations. *See, e.g.*, *Dibattista v. Buckalew, Frizell & Crevina, LLP*, 574 F. App'x 107, 113 (3d Cir. 2014) (holding that the lack of "magic words" to describe the claim in the complaint is not dispositive). Motions to dismiss turn on the sufficiency of factual, not conclusory, allegations. *See, e.g.*, *Bio-Rad Labs.*

[22] ViroPharma challenges the sufficiency of the FTC's allegations only as to the first prong. *See* D.I. 20 at 24–26.

Inc., v. Thermo Fisher Scientific Inc., --- F. Supp. 3d ---, No. 16-358-RGA, 2017 WL 438733, at *1 (D. Del. Feb. 1, 2017) (noting that detailed factual allegations are not required, but a complaint must contain more than labels and conclusions).

More importantly, the allegations show that ViroPharma's petitioning was objectively baseless. ViroPharma's citizen petition did not include any supporting clinical data. D.I. 2 ¶¶ 1, 127. The FDA concluded that ViroPharma's scientific arguments were "unsupported" and "lack[ing] merit." D.I. 2 ¶¶ 104, 122. The independent Advisory Committee Panel unanimously rejected ViroPharma's position (D.I. 2 ¶¶ 1, 85) and all of its lawsuits were withdrawn or dismissed. D.I. 2 ¶¶ 109, 125. Regardless of whether ViroPharma disputes certain facts within the Complaint, the FTC has alleged a claim of objective baselessness.

ViroPharma also argues that because it petitioned the FDA to revert to prior FDA guidance, and the FDA took several years to respond, its FDA filings could not have lacked merit. D.I. 20 at 25. But again, these arguments raise disputed facts. The FTC's Complaint alleges that the FDA's response time was due to the serial and meritless nature of ViroPharma's petitioning. D.I. 2 ¶¶ 144–45. The Complaint also alleges that ViroPharma knew it could not convince the FDA to revert to the old guidance without submitting supporting clinical data, and yet ViroPharma failed to provide any such data. D.I. 2 ¶ 50.

ViroPharma's argument that its "petitioning was successful in certain key respects" (D.I. 20 at 26) raises yet more issues of fact that cannot be resolved at this stage of the litigation. Even if ViroPharma achieved some minor success with its petitioning, a partially successful citizen petition can nonetheless be objectively baseless. For example, *In re Prograf Antitrust Litigation*, 2012 WL 293850, at *7, denied a motion to dismiss despite the FDA's having granted one of the four requests for administrative action in the defendant's citizen petition. *Prograf* held that the

complaint had sufficiently pleaded that the defendant's citizen petition was objectively baseless by alleging that the FDA found no merit to the defendant's citizen petition, in that the defendant cherry-picked the information presented, the studies cited in the citizen petition were flawed, and the relief requested in the citizen petition was unnecessary. *See id.* at *7; *see also Suboxone*, 64 F. Supp. 3d at 689 (denying a motion to dismiss a sham citizen petition claim where petitioner argued FDA partially granted its requests). In short, the Complaint plausibly alleges objective baselessness. To the extent ViroPharma disagrees with the substance of those allegations, that disagreement only highlights why dismissal is inappropriate here, where disputed facts are at the heart of ViroPharma's motion to dismiss.

CONCLUSION

For the foregoing reasons, the Court should deny ViroPharma's Motion to Dismiss.

Dated: May 25, 2017

Respectfully Submitted,

/s/ Thomas J. Dillickrath

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